DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Mr. Roger L. Richins
Vice President, Technology and Regulatory Affairs
Catheter Innovations, Incorporated
3598 West 1820 South
Salt Lake City, Utah 84104-4859

Re: K003642
Trade Name: Placement-Plus
Regulatory Class: II
Product Code: LJS
Dated: November 22, 2000
Received: November 27, 2000

Dear Mr. Richins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION(S) STATEMENT*

I state in my capacity as Vice President of Technology and Regulatory Affairs, that this notification [Special 510(k): Device Modification] for the following devices, PASV® *Placement-plus™* Polyurethane PICC Catheters is indicated for use in establishing peripheral access to the central venous system for administration of fluids including, but not limited to, hydration agents, antibiotics, chemotherapy, analgesics, nutritional therapy, and blood products. It is also indicated for blood specimen withdrawal.

The product is effective for central venous access in adults, children, and infants who require intravenous (IV) therapy.

Signature of 510(k) Submitter

Printed Name of Submitter: Roger L Richins

Date: November 22, 2000

*Suggested language and format to meet the requirements of sections 513(I) of the Federal Food, Drug, and Cosmetic Ac5t, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulatiohns, Title 21.

Concurrence of Office of Device Evaluation

K003642
510(k) Number

Division Sign-Off
Office of Device Evaluation

(Division Sign-Off)
Division of Dental, Infection Congrol,
And General Hospital Devices
510(k) Number K003642

Patricia Cicconte
(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K003642